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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/647,161 | 08/21/2003 | Alexander C. Chang | 11393-003-999 | 1544 |

20583 7590 03/22/2006

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| EXAMINER | |
|---|---|
| ALEXANDER, JOHN D | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3762 | |

DATE MAILED: 03/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/647,161 | CHANG, ALEXANDER C. | |
| | Examiner | Art Unit | |
| | John D. Alexander | 3762 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *21 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-84* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-84* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/25/05, 8/21/03*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *20060316*.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Objections*

Claims 5, 13, and 21 are objected to because of the following informalities: the phrase "the method" should be changed to --the apparatus--.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 9-29 and 31** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Regarding **Claims 9-29**, a claim which depends from a claim that "consists of" the recited elements or steps cannot add an element or step. See MPEP 2111.03.
- Regarding **Claim 31**, the limitation "the connector device" in line 1 lacks sufficient antecedent basis.

### *Claim Rejections - 35 USC § 101*

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

**Claims 72-77** are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims recite elements of data with no tangible structure or active steps. For example, it seems that the elements of Applicant's "member record" could simply read on an individual's natural memory (i.e., in the mind). It is suggested that the claims be amended to recite the elements of the member record as being stored on a tangible computer useable medium.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

**Claims 1-8, 30, and 31** are rejected under 35 U.S.C. 103(a) as being unpatentable over Feingold (Patent No. 4233987) in view of Olson et al. (Patent No. 4883064). Examiner notes that Applicant's use of the transition phrase "consisting of" actively excludes any elements that have not been specified in Claim 1.

- Regarding **Claim 1**, Feingold discloses an electrode pad for an electrocardiogram system (Figs. 1-3). Feingold discloses a further embodiment wherein one of the electrodes (Figs. 1-3; elements 22) is separated from the others and repositioned on the chest of the subject (Col. 2, lines 31-37; Col. 3, lines 3-9). Examiner considers that, within this embodiment, the two

remaining attached electrodes meet Applicant's requirements for a first non-conductive pad with first and second electrodes, and that the individual separated electrode meets Applicant's requirements for a second non-conductive pad with third electrode. Examiner further considers that the individual separated electrode (i.e. third electrode) is inherently capable of positioning close to the right arm of the subject and therefore functioning as the RA electrode. For further discussion of the function of the electrodes of the first pad, see remarks made in rejection of Claims 2-9 and 30 below. Feingold further discloses that the electrodes are connected to an electrocardiograph monitoring apparatus (Col. 1, lines 41-42; Col. 2, lines 13-15), but does not explicitly disclose that this monitoring apparatus is capable of measuring both a first lead and a different second lead without user intervention. Olson et al. disclose a electrocardiological measuring apparatus connected to first, second, and third electrodes (Fig. 1, elements 7-10; Fig. 8; Col. 5, lines 25-28), wherein the measuring apparatus automatically and sequentially measures leads from the electrodes (Col. 6, lines 46-47; Col. 7, lines 3-23). It would have been obvious to on of ordinary skill in the art at the time of Applicant's invention from the teachings by Olson et al. to modify the electrocardiogram system of Feingold to include a monitoring apparatus that is capable of measuring both a first lead and a different second lead without user intervention. The motivation would have been to allow multiple different leads to be monitored over the course of a minimized time period without requiring simultaneous monitoring or storing of the multiple lead signals (Olson et al., Col. 4, lines 61-65). Further advantages would have been to produce a smaller volume of data that can be processed and analyzed more efficiently without losing diagnostic certainty, that requires less memory, and that is more easily

communicated to trained professionals for interpretation (Col. 4, lines 65-68; Col. 5, lines 1-15).

- Regarding **Claims 2-5 and 30**, examiner considers that the pad with two remaining attached electrodes is inherently capable of placement such that one electrode represents LL and the other represents V4 or V5. Furthermore, examiner considers that, given such configurations, the system is inherently capable of measuring leads II, V4, or V5.
- Regarding **Claims 6-8**, examiner considers that the pad with two remaining attached electrodes is inherently capable of placement such that the two electrodes represent V4 and V5 and that, given such configurations, the system is inherently capable of measuring leads V4 and V5.
- Regarding **Claim 31**, Feingold further discloses that the first and second electrode pads are formed from non-conductive material such as plastic foam (Figs. 2 & 3, element 15; Col. 1, lines 65-67; Col. 2, line 28).

**Claims 32, 35, 45, and 47** are rejected under 35 U.S.C. 103(a) as being unpatentable over Feingold in view of Olson et al. as applied to Claims 1-8, 30, and 31 above, and further in view of Applicant's admitted prior art. Here, examiner notes that, for Claim 32 as well as Claims 48, 72, 78, and 84, the phrase "consisting of" appears in a clause of the claim body, rather than immediately following the preamble. Therefore, the clause limits only the element set forth in that clause (i.e. the remote capture device), and other elements are not excluded from the claim as a whole. See MPEP 2111.03.

- Regarding **Claims 32, 35, and 47**, Feingold discloses obtaining electrocardiogram measurements using the above-described system (Col. 1, line 5-8). Examiner considers the

plural electrodes are a "remote device" because they are separated from the monitoring apparatus by wires (Fig. 1, elements 23). The disclosed use of a monitoring apparatus, especially as modified by Olson et al., includes steps of analysis, which examiner further considers to anticipate Applicant's "diagnostic test" limitation. Regarding the placement of the electrodes, Feingold discloses that the electrode pad is placed at a precordial site of the patient beneath the left breast (Fig. 1; Col. 1, lines 56-59), so examiner considers that the two remaining attached electrodes (i.e. Applicant's first and second electrodes) are disclosed as representing two of V4, V5, or V6. Although, as related above, the individual separated electrode (i.e. third electrode) seems inherently capable of positioning close to the right arm of the subject and therefore functioning as the RA electrode, such positioning is not explicitly disclosed by Feingold. However, Applicant admits (e.g. Fig 3E and Page 8 of the specification) the prior art knowledge of modified 3-electrode ECG designs that employ one of the electrodes for placement on or in the vicinity of the right arm. It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the electrocardiogram system of Feingold to include positioning of the individually placed separated electrode on or close to the subject's right arm for functioning as a RA electrode. The motivation would have been to allow measurement of lead II, which is commonly desired by cardiologists.

- Regarding **Claim 45**, as related above, Feingold's pad with two remaining attached electrodes is inherently capable of placement such that one electrode represents LL and the other represents V4 or V5. However, Feingold does not explicitly disclose this positioning. Applicant admits (e.g. Fig 3E and Page 8 of the specification) the prior art knowledge of 3-

electrode, modified V5 lead systems that employ one of the electrodes for placement over the V5 position and another for placement such that it represents LL. It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the electrocardiogram system of Feingold to include positioning of the two remaining attached electrodes to attain this modified V5 configuration. The motivation would have been to provide a configuration that is commonly desired by cardiologists for ambulatory ECG monitoring.

**Claims 32, 33, 35-43, 46, 48-63, 65-71, 78, and 80-84** are rejected under 35 U.S.C. 103(a) as being unpatentable over Levin et al. (Patent No. 5724580) in view of Olson et al. and Feingold.

- Regarding **Claims 32, 33, 48-50, 78, and 84**, Levin et al. disclose a computer system and method for collecting and analyzing ECG measurement and patient risk factor data (Col. 4, lines 4-16; Col. 10, lines 56-67; Col. 11, lines 12-13 & 16-19). They also disclose the use of an ECG measuring apparatus and the transmission of the resulting data through communication networks (Col. 5, lines 10-25). However, Levin et al. does not explicitly disclose that the ECG measuring apparatus is capable of measuring both a first lead and a different second lead without user intervention. As related above, Olson et al. disclose an ECG measuring apparatus and teach this capability. It would have been obvious to on of ordinary skill in the art at the time of Applicant's invention from the teachings by Olson et al. to modify the ECG system of Levin et al. to include a monitoring apparatus that is capable of measuring both a first lead and a different second lead without user intervention. The motivation would have been to allow multiple different leads to be monitored over the course

of a minimized time period while producing a smaller volume of data that can be processed and analyzed more efficiently without losing diagnostic certainty, that requires less memory, and that is more easily communicated to trained professionals for interpretation (Col. 4, lines 65-68; Col. 5, lines 1-15). Levin et al. also disclose that the ECG measuring apparatus employs leads that are remotely connected to a subject (Col. 5, lines 10-16). However, they do not explicitly disclose the specific electrode lead configuration claimed by Applicant. As related above, Feingold discloses an ECG electrode embodiment that includes first and second electrodes on a single pad and placed in the V4, V5 or V6 positions, and a separate, individually placed third electrode. It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the ECG system of Levin et al. to include the electrode pad configuration taught by Feingold. The motivation would have been to provide an electrode configuration that permits effective application, without stretching or distortion, to any curved portion of the chest or thorax of a patient of any age or size (Feingold, Col. 1, lines 33-36).

- Regarding **Claims 35-37 and 52-56**, Levin et al. further disclose obtaining record information including patient ID, birth date, sex, and weight and obtaining the results of diagnostic tests including risk factor information such as cigarette smoking, blood pressure, cholesterol levels, and diabetic condition (Col. 5, lines 2-7; Col. 8, line 67).
- Regarding **Claims 38-42, 46, 58-62, 71, and 80-83**, Levin et al. further disclose using ECG analysis and risk factor information to perform pre-screening for identification of abnormalities such as ischemia (Col. 10, lines 56-67; Col. 11, lines 12-13, 16-19, 35-39, & 53-64).

- Regarding **Claims 43 and 63**, Levin et al. further disclose providing a report of the collected data, including ECG measurement, using a web site (Col. 6, lines 9-10).
- Regarding **Claim 51**, Levin et al. further disclose that the ECG data is digitized (Col. 4, lines 37; Col. 5, lines 20-21).
- Regarding **Claims 65-69**, Levin et al. further disclose a database that includes member records with the collected patient identifiers, personal record information, risk factor information, and pre-screening identification (Col. 6, lines 3-15).

**Claims 34, 44, 64, and 79** are rejected under 35 U.S.C. 103(a) as being unpatentable over Levin et al. in view of Olson et al. and Feingold as applied to Claims 32, 33, 35-43, 46, 48-63, 65-71, 78, and 80-84 above, and further in view of Kirshner (Patent No. 6322504).

- Regarding **Claims 34 and 79**, Levin et al. do not explicitly disclose that the risk factor information is collected in the form of a questionnaire. Kirshner discloses a computerized system and website for determining a patient's risk factors for developing disease that also includes the collection of ECG data. Kirshner also teaches the use of a questionnaire to determine the risk factors (Col. 2, lines 39-42; Col. 12, lines 15-40). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention from the teachings by Kirshner to modify the risk factor collection of Levin et al. to include a questionnaire. The motivation would have been to provide an efficient means to collect the risk factor information that removes the possibility that one of the many pertinent risk categories could be forgotten or overlooked through human error.
- Regarding **Claims 44 and 64**, Levin et al. do not explicitly disclose that the website database is secured with user identification and password. Kirshner further teaches that a patient

information website should be secured with user identification and password login. It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention from the teachings by Kirshner to modify the website database access of Levin et al. to include user identification and password. The motivation would have been to insure that private patient information is only accessible to authorized users as well as to enable saving prior website activity to a particular user for easy access during return visits.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Alexander whose telephone number is (571) 272-8756. The examiner can normally be reached on Monday-Friday, 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JDA

JEFFREY R. JASTRZAB
PRIMARY EXAMINER
5/20/06